


EXHIBIT 16

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2001 WL 454586

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United States District Court, E.D. Pennsylvania.

In re: DIET DRUGS ([Phentermine](#), Fenfluramine, Dexfenfluramine) Products Liability Litigation

No. MDL 1203.

|
Feb. 1, 2001.

MEMORANDUM AND PRETRIAL ORDER NO. 1685

[BECHTLE](#), J.

*1 Presently before the court are American Home Products Corporation's ("AHP") motions to exclude and/or limit the expert testimony of John J. La Puma, M.D., Colin M. Bloor, M.D., James Oury, M.D., John Gueriguian, M.D., Arthur H. Hayes, M.D., Robyn J. Barst, M.D., Stuart Rich, M.D. and Barry Sears, Ph.D.; the Plaintiffs' responses thereto; and AHP's and Plaintiffs' Pretrial Order No. 1468 memoranda and accompanying appendices. For the reasons set forth below, the court will grant the motions to exclude the testimony of Drs. La Puma, Bloor and Oury. The court will grant in part and deny in part the motions to exclude the testimony of Drs. Gueriguian, Hayes, Barst, Rich and Sears.

I. BACKGROUND

Plaintiffs have offered all of these witness as generic experts for civil actions in this MDL No. 1203. Their testimony covers issues including the health risks and benefits, efficacy, and labeling of the diet drugs [Pondimin](#)¹ and [Redux](#).² AHP challenges several of the opinions put forth by these witnesses.

It should be noted that the parties were advised that all of these witnesses' expert opinions should be presented to this court and articulated on the record, that it was expected that these would be the principal opinions offered at trial, and that this court would rule on the admissibility of those opinions. The court believes that this process will enhance judicial

economy by disposing of *Daubert*³ issues applicable to the vast majority of cases within this MDL No. 1203.

With that in mind, the court will: (1) address some practical concerns surrounding the instant motions; (2) delineate the scope of the court's ruling by discussing certain categories of challenges to these witnesses' testimony that, in the court's opinion, do not implicate [Federal Rules of Evidence 702 & 703](#) or *Daubert*, or have already been addressed by the court in prior rulings; (3) set out the standard for admissibility of expert testimony; and finally (4) discuss the specific *Daubert* challenges to the testimony of each witness and the court's rulings thereon.⁴

A. Practical Concerns

The court must revisit and address, as it did in Pretrial Order No. 1332, the unique situation presented by the context in which these *Daubert* motions were presented. It is important that the remand courts understand the unusual circumstances faced by this transferee court with regard to the *Daubert* issues raised by the testimony of expert witnesses who may testify by video in many proceedings throughout the country.

First, the court incorporates by reference its discussion in Pretrial Order No. 1332 concerning the difficulties that the remand courts will face regarding the potential necessity of redacting and/or modifying the trial deposition⁵ videos based on evidentiary rulings. (Pretrial Order No. 1332 at 17–19.)

Second, another unusual circumstance is that when a trial deposition video is made, certain positions are taken by the expert during direct and cross-examination that are intended to cover all issues upon which the expert could be called to testify, covering a full range of issues for many plaintiffs, even though only excerpts of the trial deposition testimony may ultimately be offered for specific plaintiffs at different trials, in different places, and at different times. This circumstance necessarily leads to lengthy depositions and magnifies *Daubert* concerns.

*2 Third, unlike the usual trial witness, events may occur between the trial deposition and trial that affect a trial deposition witness's testimony, which a remand court will be asked to consider.

Fourth, because the expert's trial deposition is taken many months or even years before trial, the expert may opine or read

from documents, or portions thereof, that ultimately may not be received into evidence by the remand court.

Finally, this generic testimony may not satisfy state law requirements that will shape issues differently in different jurisdictions on issues driven by state law, such as negligence, the presence or absence of a defect, failure to warn, punitive damages and the like.

The ultimate point is that a *Daubert* ruling in this MDL transferee court may ultimately be of final and uniform value in many, many cases but is not likely to be an all encompassing ruling that provides final and clear lines of admissibility with regard to all aspects of these witnesses' testimony in all cases. For this reason, similar to Pretrial Order No. 1332, the court's ruling should be expected to cover those issues that can and should be addressed in this transferee court, yet leave open those items pertaining to the expert witnesses that can only be fairly determined by each individual remand court.

B. Non-Daubert Challenges and Issues Previously Addressed by the Court

AHP makes evidentiary challenges to the testimony of a number of these witnesses that fall outside the scope of *Daubert* or that were already addressed by the court with respect Drs. Avorn and Rubin in Pretrial Order No. 1332.⁶ These include challenges to: testimony concerning the intent, beliefs or credibility of AHP personnel or FDA officials;⁷ the reading of documents into the record without rendering an opinion thereon; the use of the regulatory term “serious” in a non-regulatory context; injection of inadmissible hearsay into trial deposition testimony; and testimony on topics not timely disclosed in the expert's report.

The court addressed the issue of expert testimony about corporate intent in Pretrial Order No. 1332. The court incorporates by reference its reasoning and ruling in that Order, to wit: (1) any proffered *expert* testimony concerning the intent of AHP or any other entity (such as the FDA) shall be excluded on the basis that the question of intent is to be determined by the jury, not experts; and (2) the court's ruling does not preclude the introduction of otherwise admissible evidence of the intent of AHP or FDA leadership or personnel. (Pretrial Order No. 1332 at 21–23.) Accordingly, AHP's motions to exclude the testimony of Drs. La Puma, Oury, Gueriguian, Hayes, Barst, Rich, and Sears will be granted to the extent that they seek to exclude *expert* opinions that

conclude what the corporate intent of AHP and/or what the beliefs of FDA officials were on matters upon which they spoke or acted.

The court has also addressed the issue of the introduction of documents and other testimony into the witnesses' trial deposition testimony. *Id.* at 20–21. The court incorporates by reference the reasoning and ruling of Pretrial Order No. 1332 with respect to this issue. Accordingly, the court will deny AHP's motions to preclude such testimony. The remand courts are the appropriate fora for these challenges.

*3 Similarly, challenges to the use of the term “serious” and the injection of inadmissible hearsay into trial deposition testimony should be left to the remand courts to rule upon at the proper time. These challenges do not implicate *Daubert*⁸ and call for particularized rulings in the context of a specific trial. For example, a court's ruling on a hearsay challenge obviously depends in part on what particular point of fact that testimony is offered to prove. Likewise, a ruling on whether the use of the term “serious” is misleading, and any corresponding remedy, is highly dependent on the context in which that testimony is offered. This court cannot anticipate the specific context in which this testimony will be offered, or the purposes for which it will ultimately be offered. Accordingly, to the extent that AHP's motions seek to exclude this testimony, they will be denied.

Lastly, the lengthy and exhaustive nature of trial deposition testimony makes it likely that during direct or cross-examination, the witness will opine on certain issues that may not have been disclosed in the witness's expert report. The court acknowledges that opinions not timely disclosed in an expert report may often, but not always, be barred from admission at trial. *See Fed.R.Civ.P. 37(c)(1)* (providing that party that without substantial justification fails to disclose information required by Rule 26(a) shall not, unless failure is harmless, be permitted to use as evidence any information not so disclosed). However, assuming that the disputed testimony is otherwise admissible, whether it is fundamentally unfair to admit it will involve practical considerations shaped largely by the context of a particular case and is a decision best left to the discretion of each trial judge. Accordingly, to the extent that AHP's motions seek to preclude certain testimony as not timely disclosed in an expert report, the motions will be denied.⁹

C. Plaintiffs' Proposed Experts

1. John J. La Puma, M.D.

Dr. La Puma is a medical doctor and professor of nutrition who claims to be an expert in “truth, honesty and integrity” in the context of medical ethics. (Tr. 12/5/00 at 202.) He has extended post doctoral education in clinical medical ethics, and is currently a senior scholar at the MacLean Center for Clinical Ethics in Chicago.¹⁰ *Id.* at 152–53. Dr. La Puma has performed between 700 and 800 clinical ethical consultations, which involve the study and potential resolution of ethical issues in individual patient cases. *Id.* at 154. Plaintiffs plan to offer the following opinions of Dr. La Puma:

* AHP failed to adequately warn about the risks of **primary pulmonary hypertension** (“PPH”);

* AHP failed to warn about the risks of **valvular heart disease** (“VHD”);

* AHP's failure to warn about the association between these diseases and the use of **Pondimin** and Redux was in conscious disregard of the health and safety of its customers;

*4 * AHP's failure to provide adequate warnings violated several industry standards and AHP's own written code of conduct;

* In failing to warn about PPH and VHD, AHP acted in its own best interests rather than in the best interests of patients; and

* AHP's failure to warn about PPH and VHD made it impossible for physicians to obtain written informed consent from their patients before prescribing the drugs.

Id. at 138–39. AHP characterizes Dr. La Puma's testimony as addressing corporate intent and deficiencies in AHP's corporate conduct. *Id.* at 140–41. AHP seeks to exclude Dr. La Puma's testimony in its entirety on the basis that it is irrelevant, that Dr. La Puma lacks expertise and reliable methodology, and that Dr. La Puma bases his testimony on his subjective, personal views. *Id.* at 144.

2. Colin M. Bloor, M.D.

Dr. Bloor is a pathologist who is currently Distinguished Professor of Pathology at the University of California, San Diego. (Tr. 12/12/00 at 164–65.) Dr. Bloor opines that:

* dexfenfluramine caused a statistically significant increase in the incidence and severity of myocardial fibrosis in the

hearts of rats that were part of Study 1781, a 1988–90 dexfenfluramine (Redux) carcinogenicity study conducted by Servier (“Study 1781”);

* **fenfluramines** caused myocardial fibrosis in human hearts; and

* the increased incidence and severity of myocardial fibrosis was a strong signal that dexfenfluramine possesses cardiotoxic properties and the results of Study 1781 mandated further testing before the drug was marketed.

Id. at 159. AHP does not dispute that Dr. Bloor is highly qualified in the field of pathology. However, AHP seeks to exclude these opinions on grounds that: (1) they were arrived at through a scientifically unreliable methodology; (2) they do not “fit” the facts of this litigation; and (3) Dr. Bloor lacks the requisite qualifications to render opinions regarding some of the subjects about which he testifies. *Id.* 159–62.

3. James Oury, M.D.

Dr. Oury is a cardiac surgeon who specializes in thoracic and **cardiovascular surgery**, with particular emphasis in the surgical treatment of **valvular heart disease**. *Id.* at 15–17. He practices at the International Heart Institute of Montana, of which he was a founder, at St. Patrick Hospital in Missoula, Montana. *Id.* at 18. Plaintiffs propose to offer, and AHP challenges, Dr. Oury's testimony that:

• reports of VHD in **Pondimin** users received by AHP in 1995 should have triggered further testing, evaluation and warnings to physicians concerning **Pondimin**;

• reports of VHD in **Pondimin** users should have triggered further testing, evaluation and warnings to physicians concerning Redux; and

• the findings of fibrosis in the hearts of rats in Servier's Study 1781 notified AHP of the potential for **fenfluramines** to cause similar problems in humans.

Id. at 9–10. AHP characterizes Dr. Oury's testimony as encompassing opinions on labeling and regulatory issues, and pathology.¹¹ *Id.* at 5.

4. John L. Gueriguian, M.D.

*5 Dr. Gueriguian is a medical doctor, pharmacologist, endocrinologist and chemist who was employed by the United States Food and Drug Administration (“FDA”) from

1978 to 1998 in the Division of Endocrine and Metabolic Drug Products. (Tr. 12/5/00 at 281–82.) In that capacity, he reviewed drugs for safety and efficacy; applied FDA regulations regarding labeling, postmarketing surveillance and approval of drugs; and participated to some extent in the drafting of those regulations. *Id.* at 282. Plaintiffs propose to offer, and AHP challenges, Dr. Gueriguian's opinions that:

- drug safety surveillance is important to the public because “patients themselves should have an opportunity to voice their opinion and make a decision ... to be able to read and understand the labeling, particularly when explained by the prescribing physician”;
- pharmaceutical companies have a responsibility to provide information in a clear and understandable way to the FDA;
- a medical officer, such as Dr. Lutwak of the FDA, would have recognized certain adverse event information as a signal of problems with these diet drugs;
- AHP's failure to provide a warning regarding VHD in [Pondimin](#) or Redux labeling before 1997 resulted in more people suffering or dying; and
- rely on the report of Dr. Bloor concerning his findings and conclusions based on his analysis of the data from Study 1781.

Id. at 296–302; AHP's Reply in Supp. of Mot. to Limit the Test. of Pls.' Generic Expert John Gueriguian, M.D. (“Reply re: Gueriguian”) at 6–11. AHP challenges this testimony on grounds that Dr. Gueriguian: (1) offers his personal opinions as if they were expert opinions; (2) improperly speculates as to what others would do with adverse event information; and (3) improperly “parrots” the opinion of another expert. (AHP's PTO 1468 Mem. in Supp. of Mot. to Exclude the Expert Ops. of John L. Gueriguian, M.D. (“AHP's PTO 1468 Mem. re: Gueriguian”) at 5–9.)

5. Robyn J. Barst, M.D. and Stuart Rich, M.D.

Dr. Barst is a pediatricist and pediatric cardiologist. (AHP's Mot. to Exclude Expert Test. of Robyn J. Barst, M.D. (“Mot. re: Barst”) Ex. A.) She is also the Director of the New York Presbyterian Pulmonary Hypertension Center at Columbia–Presbyterian Hospital in New York, which follows about 3,000 patients with [pulmonary hypertension](#) (“PH”) per year. (Pls.' Opp'n to Defs.' Mot. to Exclude Expert Test. of Robyn J. Barst, M.D. (“Opp'n re: Barst”) Ex. 2.) In that capacity, Dr.

Barst studies the pathogenesis and pathophysiology of PH. *Id.* at 3–4.

Dr. Rich, an internist and cardiologist, is a Professor of Medicine at the Rush Medical College and Senior Attending Physician at the Rush–Presbyterian–St. Luke's Medical Center in Chicago. (Pls.' Opp'n to Defs.' Mot. to Exclude Expert Test. of Stuart Rich, M.D. (“Opp'n re: Rich”) Ex. 2 at 1.) He is also the Director of the Rush Heart Institute's Center for Pulmonary Heart Disease, and Coronary Heart Disease Detection and Treatment Center in Chicago. *Id.* Ex. 2 at 2. Dr. Rich is involved in epidemiologic research regarding the causes and treatment of PH, PPH and [Secondary Pulmonary Hypertension](#) (“SPH”). (Opp'n re: Rich at 3.) He has treated over 3,000 PH patients, hundreds of whom suffered from PPH. *Id.* Dr. Rich has also consulted drug companies regarding the risks of PPH posed by diet drugs, and testified before an FDA advisory committee at hearings concerning the approval of Redux. *Id.* at 5 & Ex. 2 at 5.

*6 AHP challenges these witnesses' opinions concerning:

- labeling and AHP's non-compliance with FDA regulations; and
- [obesity](#) and the efficacy of [Pondimin](#) and Redux for treating [obesity](#).

(AHP's PTO 1468 Mem. in Supp. of Mot. to Exclude the Expert Ops. of Robyn J. Barst, M.D. (“AHP's PTO 1468 Mem. re: Barst”) at 8–11; AHP's PTO 1468 Mem. in Supp. of Mot. to Exclude MDL Ops. of Stuart Rich, M.D. (“AHP's PTO 1468 Mem. re: Rich”) at 9–12.) AHP asserts as grounds for these challenges that Drs. Rich and Barst are not qualified to render opinions on these subjects and did not utilize a reliable methodology in arriving at their conclusions.

6. Barry Sears, Ph.D.

Dr. Sears is a molecular biologist who researches the molecular and hormonal bases of [obesity](#). He has specialized for twenty-five years in the study of lipids, lipid proteins, and [insulin](#), and their effects on morbidity and mortality. (Tr. 2/12/00 at 87.) Dr. Sears is the author of *The Zone*, a book that addresses the potentiality of diet to reduce [insulin](#) and other hormones that relate to [heart disease](#), Type II [diabetes](#), and other conditions. (Tr. 12/13/00 at 128–29.) Dr. Sears will testify about, *inter alia*,

- the importance of accounting for reduction of excess fat when undertaking clinical studies;

- the imprecise methods of measuring fat utilized by some clinical studies of anorectic agents (diet drugs);
- the inefficacy of [Pondimin](#) and Redux for reducing fat; and
- the comparative effectiveness of diet drugs versus diet and exercise for reducing [obesity](#) and its comorbidities.

(Tr. 12/12/00 at 88–89.) AHP characterizes Dr. Sears' testimony as addressing the medical treatment of [obesity](#); whether [Pondimin](#) and Redux met FDA efficacy standards for approval; and AHP's marketing and disclosure obligations. (AHP's PTO 1468 Mem. in Supp. of Mot. to Exclude the Expert Ops. of Barry Sears, Ph.D. ("AHP's PTO 1468 Mem. re: Sears") at 1.) AHP asserts that Dr. Sears lacks expertise in medicines generally and in the medical treatment of [obesity](#) specifically. *Id.* at 90.

II. LEGAL STANDARD

The court incorporates herein its extended discussions of the standard for admissibility of expert evidence in Pretrial Orders Nos. 1332 and 1351. Thus, the court will only briefly review that standard here.

[Federal Rule of Evidence 702](#) obligates judges to ensure that any scientific testimony or evidence admitted is relevant and reliable.¹² [Kumho Tire Co., Ltd. v. Carmichael](#), 526 U.S. 137, 147 (1999) (quoting [Daubert](#), 509 U.S. at 589). The party offering the expert has the burden of proving admissibility. [Daubert](#), 509 U.S. at 592 n. 10. The subject of an expert's testimony must be grounded in the methods and procedures of science and based on more than subjective belief or speculation. [Id.](#) at 589–590. Further, [Rule 702](#) requires that expert testimony assist the trier of fact, i.e., it must "fit" the issues in the case by having a "valid scientific connection to the pertinent inquiry." *Id.* at 591–92.

*7 In determining "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact," the court must assess whether the methodology underlying the testimony is scientifically valid and whether it can properly be applied to the facts in issue. *Id.* at 592–93. Furthermore, the court must examine the expert's conclusions in order to determine whether they can reliably follow from the facts

known to the expert and the methodology used. [Heller v. Shaw Indus., Inc.](#), 167 F.3d 146, 153 (3d Cir.1999).

In *Daubert*, the Court identified several factors to assist courts in evaluating whether a scientific theory or methodology constitutes reliable scientific knowledge. These include: whether the theory or technique can be or has been tested; whether the theory has been subjected to peer review and publication; whether a technique has a known or potential rate of error and whether there are standards controlling the technique's operation; and whether the theory or method has general acceptance in the scientific community.¹³

[Daubert](#), 509 U.S. at 593–94. These factors "are simply useful signposts, not dispositive hurdles that a party must overcome in order to have expert testimony admitted."

[Heller](#), 167 F.3d at 152.

In addition, a court should "exclude proffered expert testimony if the subject of the testimony lies outside the witness's area of expertise." 4 Weinstein's Fed. Evid. § 702.06[1], at 702–52 (2000). In other words, a party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue. [Redman v. John D.](#)

[Brush and Co.](#), 111 F.3d 1174, 1179 (4th Cir.1997); [Barrett v. Atl. Richfield Co.](#), 95 F.3d 375, 382 (5th Cir.1996).

Moreover, testimony of an expert that constitutes mere personal belief as to the weight of the evidence invades the province of the jury. [McGowan v. Cooper Indus., Inc.](#), 863 F.2d 1266, 1273 (6th Cir.1987); [STX, Inc. v. Brine, Inc.](#), 37 F.Supp.2d 740, 768 (D.Md.1999) (quotation omitted), *aff'd*, 211 F.3d 588 (Fed.Cir.2000), *aff'd*, No. 99–1540, 2000 WL 564010 (Fed.Cir. May 8, 2000); [Sec. and Exch. Comm'n v. Lipson](#), 46 F.Supp.2d 758, 763 (N.D.Ill.1998).

Lastly, the court "should also be mindful of other applicable rules." [Daubert](#), 509 U.S. at 595. [Federal Rule of Evidence 703](#) "provides that expert opinions based on otherwise inadmissible hearsay are to be admitted only if the facts and data are 'of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject.'" *Id.* (quoting [Fed.R.Evid. 703](#)). Under [Rule 703](#), "[i]f the underlying data are so lacking in probative force and reliability that no reasonable expert could base an opinion

on them, an opinion which rests entirely upon them must be excluded.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 748 (quoting *In re “Agent Orange” Prod. Liab. Litig.*, 611 F.Supp. 1223, 1245 (E.D.N.Y.1985)).

III. DISCUSSION

*8 The court will address the particular challenges to each witnesses' testimony, the plaintiffs' responses and the court's ruling on each challenge.

A. Dr. La Puma

Dr. La Puma testified that the labeling for Redux and Pondimin was false, misleading, deceptive and inaccurate and that AHP should have included certain labeling restrictions imposed by the French Medicine Agency in its warning. (AHP's Mot. to Exclude the Test. of Pls.'s Generic Ethics Expert John J. La Puma, M.D. (“Mot. re: La Puma”) at 17–19.) AHP argues that Dr. La Puma has no basis for testifying about what should be in a label as he has no expertise in the applicable legal standards or the process of determining a label's content. *Id.*

Dr. La Puma also testified about AHP's alleged miscoding and failure to report adverse drug events (“ADEs”), his interpretation of Study 1781 and his belief that AHP failed to warn of the risk of VHD. *Id.* at 20–25. AHP claims that Dr. La Puma has no expertise in ADE reporting and is unfamiliar with the ADE coding system used by the FDA and pharmaceutical companies. *Id.* at 20. Also, AHP asserts that his testimony that Servier's Study 1781 showed focal fibrosis in rat hearts is speculation because he is not a pathologist and never reviewed the slides. *Id.* at 22.

Plaintiffs respond that it is the participation of AHP's doctors and in-house physicians in decision making that necessitates Dr. La Puma's testimony regarding AHP's medical ethics and the issue of informed consent. (Pls.' Mem. of Law in Opp'n to AHP's Mot. to Exclude the Test. of Pls.' Generic Ethics Expert John J. La Puma, M.D. (“Opp'n re: La Puma”) at 9–10.) According to Plaintiffs, medical ethics, particularly informed consent, are unfamiliar to a jury and are appropriate for expert testimony. *Id.* at 14. Plaintiffs argue that testimony regarding breach of ethical duties can help the jury determine the standard of care and whether it was breached. *Id.* at 19–22. Moreover, Plaintiffs assert that Dr. La Puma's testimony about Pondimin and Redux labels focuses on what a prescribing

doctor does with a label and that doctor's expectations regarding what the label should say. *Id.* at 30–32.

AHP replies that this case involves specialized issues concerning a pharmaceutical company's conduct, not informed consent. (AHP's Reply Mem. in Supp. of Mot. to Exclude the Expert Test. of Pls.' Generic Ethics Expert John J. La Puma, M.D. (“Opp'n re: La Puma”) at 2.) According to AHP, “derivative expertise,” i.e., alleged expertise about corporate conduct derived from expertise in the ethics of informed consent or the general practice of internal medicine, does not make Dr. La Puma's testimony admissible. *Id.* at 2 & 13. AHP points out that the pharmaceutical industry has its own standards and customs that differ from the issues that arise in a doctor-patient setting. *Id.* at 6. Lastly, AHP challenges Dr. La Puma's qualifications to address what information should have been provided to doctors because there is no scientific evaluation or investigation underlying his opinions. *Id.* at 7–12.

*9 The court concludes that Dr. La Puma's testimony cannot withstand scrutiny under *Daubert*.

First, Dr. La Puma's expertise and experience in clinical medical ethics are, at best, only marginally relevant to AHP's conduct in the manufacturing and marketing of diet drugs. The court agrees with AHP that the pertinent issues in this litigation are the obligations of a pharmaceutical company in testing, surveying and labeling medications.¹⁴ (Tr. 12/5/00 at 252.) Also, proof that a pharmaceutical company has fulfilled all ethical requirements is not an essential element in proving informed consent. Dr. La Puma's expertise, garnered largely from the study of medical ethical issues in individual patient cases, simply does not qualify him to render opinions concerning the appropriate conduct of pharmaceutical companies in the manufacture and marketing of drugs. Pharmaceutical company conduct is governed by extensive regulations of which Dr. La Puma has little or no knowledge. *See id.* at 203–215 & 228–233 (reflecting Dr. La Puma's lack of experience in matters relating to, *inter alia*, drug development, testing, safety surveillance, adverse event monitoring, label drafting and evaluation, and FDA regulations). Furthermore, Dr. La Puma has, at best, only incidental experience with pharmaceutical industry standards regarding what information should be communicated by drug companies to physicians about the risks and benefits of drugs. *See id.* at 156 (reflecting Dr. La Puma's testimony that his understanding of such standards comes primarily from experience as practicing physician and stating generally

that he “encounter[s] drug detail people all the time, and actually [has] in [his] own work found that the information to be provided must be comprehensive and reliable and accurate and truthful”). Dr. La Puma also lacks expertise in the medical specialties that would qualify a witness to testify about the accuracy and appropriateness of warning labels, the medical significance of adverse event reports, and the risks of PH, PPH and VHD posed by [Pondimin](#) and [Redux](#). He has no expertise in cardiology, pathology, pulmonology or toxicology. *Id.* at 228–233. Neither Dr. La Puma's experience as a practicing physician nor his study of informed consent are sufficient to qualify him as an expert in the application of pharmaceutical industry standards for warning of the adverse health effects of drugs. *See Tyler v. Sterling Drug Co.*, 19 F.Supp.2d 1239, 1245 (N.D.Okla.1998) (rejecting notion that general concepts of informed consent equate to specific industry standards for warning labels). Thus, he is not qualified to offer opinions about the accuracy of labels or the appropriateness of AHP's conduct concerning its alleged failure to warn doctors, patients or the FDA about risks of heart maladies posed by these drugs.

Second, to the extent that the doctrine of informed consent may be pertinent, it is measured by a *legal* standard. This standard varies among the numerous jurisdictions whose substantive law governs the individual cases in this MDL No. 1203. Dr. La Puma does not have the knowledge or expertise concerning the legal standard of informed consent as defined by each of these particular jurisdictions.

***10** Third, before being retained by Plaintiffs in this litigation, Dr. La Puma had virtually no experience with the interpretation or application of the various voluntary codes of conduct that he claims AHP violated. (Tr. 12/5/00 at 224–25.) He had never even seen a pharmaceutical company's code of conduct, including AHP's. *Id.* at 225.

Fourth, the court fails to see how Dr. La Puma's testimony could assist the trier of fact determine a matter in dispute. Assuming, *arguendo*, that the voluntary codes of conduct about which Dr. La Puma testifies are relevant to a pharmaceutical company's standard of care in the context of drug development and marketing, Dr. La Puma himself testified that anyone who reads and understands the English language can interpret and apply them. *Id.* at 227–28. Thus, his testimony on the subject is unnecessary. *See Fed.R.Evid.* 702 advisory committee's notes (quoting Ladd, Expert Testimony, 5 Vand. L.Rev. 414, 418 (1952)) (stating that “ ‘[t]here is no more certain test for determining

when experts may be used than the common sense inquiry whether the untrained layman would be qualified to determine intelligently ... the particular issue without enlightenment from those having a specialized understanding of the subject” ’).

Finally, the court has serious doubts about the reliability of the methodology employed by Dr. La Puma in arriving at his conclusions. He testified that:

I read as much as possible about the industry standards and medical codes of conduct and these particular codes ... and tried hard to think about and derive what and how an ethical company would act and then compared it with the information I have received ... about how AHP ... acted.

(PTO 1468 App. of Materials for Consideration of AHP's Daubert Mot. to Exclude Expert Test. of John J. La Puma, M.D., Vol. I (“PTO 1468 App. re: La Puma I”), Tr. 8/6/99 at 117.) Even if this method is informed by his experience in the field of medical ethics, its reliability is dubious. Despite Dr. La Puma's testimony that any medical ethicist employing his methodology would arrive at the same conclusions, the court finds this method to be inherently susceptible to subjective personal influence and lacking indicia of reliability.

For all of these reasons, the court will grant AHP's motion to exclude the testimony of Dr. La Puma.

2. Dr. Bloor

Dr. Bloor opines that: (1) dexfenfluramine caused a statistically significant increase in the incidence and severity of myocardial fibrosis in the hearts of rats in Study 1781; (2) [fenfluramines](#) caused myocardial fibrosis in human hearts; and (3) the increased incidence and severity of myocardial fibrosis was a strong signal that dexfenfluramine possesses cardiotoxic properties and the results of Study 1781 mandated further testing before the drug was marketed. The primary basis of Dr. Bloor's opinions is his review of cardiac tissue slides from rats that were part of Study 1781. AHP argues that Dr. Bloor's methodology is not scientific, his opinions do not fit the facts of this litigation, and that Dr. Bloor lacks

the requisite expertise to render these opinions. The court will set forth the respective contentions of the parties regarding each of these issues, and then address the admissibility of the challenged opinions.


1. The Parties' Arguments

a. Methodology

*11 Dr. Bloor visually observed the slides from Study 1781 and recorded narrative descriptions of what he saw in each. (Br. of AHP in Supp. of Mot. to Exclude Expert Test. of Colin M. Bloor, M.D. ("Mot. re: Bloor") at 12.) He organized those descriptions into verbal categories and collapsed and converted the categories into numerical scores. *Id.* Each step was done without reexamining the slides. *Id.* Because the slides were not cut in a manner that would best reveal heart structures, Dr. Bloor could only comment to a reasonable degree of medical certainty as to the myocardium of the rats' hearts, and not the valves.¹⁵ (PTO 1468 App. of Materials for Consideration of AHP's Daubert Mot. to Exclude Expert Test. of Colin M. Bloor, M.D., Vol. I ("PTO 1468 App. re: Bloor I"), Tr. 2/21/00 at 632–33 & 654–55.)

AHP asserts that Dr. Bloor's methodology is unreliable because: he began his analysis with the assumption that dexfenfluramine is cardiotoxic, rather than starting with the null hypothesis¹⁶ that dexfenfluramine is not cardiotoxic; uses data from Study 1781 for a purpose other than what was intended; Dr. Bloor's "semi-quantitative" scoring of degrees of fibrosis is subjective, conducted without blinding, and unrepeatable or falsifiable; and his analysis failed to account for confounding factors such as age, stress, diet or other cardiac pathology. (Tr. 12/12/00 at 159–60).

Plaintiffs assert that much of Dr. Bloor's career consists of analyzing histological slides such as those in Study 1781. (Pls.' Mem. in Resp. to AHP's Br. in Supp. of Mot. to Exclude the Expert Test. of Colin M. Bloor, M.D. ("Resp. to Mot. re: Bloor") at 6.) About 40% of Dr. Bloor's time is spent doing lab research, and he sees 240 to 600 rodent heart slides a year. *Id.* According to Plaintiffs, his methodology is utilized by other cardiopathologists, including some who have been retained by the parties in this litigation. *Id.* at 32. Plaintiffs contend that the concept of a null hypothesis is inapplicable to a review of slides from another pathologist's study, particularly where the authors of the study reached the same conclusion that the slides demonstrated a significant increase in the level of fibrosis found in the rats' hearts. *Id.* at 31. Thus, Plaintiffs

argue, Dr. Bloor properly reasoned from known facts to reach a conclusion. *See id.* (quoting  *Sorenson v. Shaklee Corp.*, 31 F.3d 638 (8th Cir.1994)). Plaintiffs also assert that because Dr. Bloor is testifying that the Servier study results should have prompted further testing, his failure to account for confounding factors does not render his methodology or ultimate opinion unreliable. *Id.* at 50.

b. "Fit"

AHP argues that Dr. Bloor's observations of myocardial fibrosis from a single rat study do not fit the distinctive heart valve pathology observed in some patients who have taken *fenfluramines*. (Tr. 12/12/00 at 160; Mot. re: Bloor at 28–29.) According to AHP, these findings cannot be extrapolated to humans because of the dramatic differences in physiology and dosage levels, and studies of animals exposed to massive doses of a drug are not reliable evidence of causation in humans. (Mot. re: Bloor at 28 & 30–33.) Besides his analysis of the Servier study, Dr. Bloor relies on anecdotal case reports, which are generally recognized as unreliable. *Id.* at 33–37. Thus, AHP argues that Dr. Bloor's extrapolation from animal findings of myocardial fibrosis, a condition not reported in the human literature, to the conclusion that *fenfluramine* causes endocardial fibrosis, valvular thickening, and chordal changes in humans is unjustified. *Id.* at 33.

*12 Plaintiffs respond that Study 1781 was relied on by the FDA when it approved Redux. (Resp. to Mot. re: Bloor at 57.) They also claim that Dr. Bloor essentially "peer reviewed" the work of Dr. Boivin, one of the original investigators, and relied on the same methodology. (Pls.' PTO 1468 Mem. re: Bloor Ex. D–2.) Also, Plaintiffs note that AHP's expert, Dr. Fisher, acknowledges that fibrosis is scarring whether it appears in the heart wall or heart valve—thus AHP was on notice of the fibrogenic properties of *fenfluramines*. *Id.*; Resp. to Mot. re: Bloor at 56. Lastly, Plaintiffs assert that extrapolation from rats to humans is proper because the purpose of Study 1781 was to determine whether dexfenfluramine was fit for humans. (Resp. to Mot. re: Bloor at 57.)

c. Expertise to render opinions about the fibrogenic properties of *fenfluramines* and AHP's duty to conduct further testing before marketing *Pondimin* and *Redux*



Dr. Bloor testified that *fenfluramine* and dexfenfluramine possess fibrogenic properties and thus required further testing before being marketed. (Tr. 12/12/00 at 161–62.) AHP asserts

that Dr. Bloor is not an expert on diet drugs, has never researched diet drugs or the fibrogenic properties of any drug, and has little if any experience with toxicity or carcinogenicity studies. *Id.* at 161; Mot. re: Bloor at 38–41.

Plaintiffs argue that Dr. Bloor's cardiopathology expertise and his years of experience with pathology on mice and rats qualify him to render these opinions. (Pls.' Mem. Pursuant to Pretrial Order No. 1468 Regarding AHP's Daubert Mots. ("Pls.' PTO 1468 Mem.") Ex. D–2 .) Thus, Plaintiffs claim that Dr. Bloor is qualified to testify that Study 1781 put AHP on notice of the need for additional testing to determine if fibrosis would occur in humans. (Resp. to Mot. re: Bloor at 59.)



2. The Court's Analysis

The court concludes that the challenged testimony is inadmissible under *Daubert*. The court recognizes, as do the parties, that Dr. Bloor is highly qualified in the field of cardiac pathology. However, Dr. Bloor's opinions that his review of the slides from Study 1781 demonstrated a statistically significant increase in fibrosis sufficient to notify AHP of potential problems with [fenfluramines](#) and that dexfenfluramine causes cardiac fibrosis in humans cannot withstand *Daubert* scrutiny because they cannot “reliably flow from the facts known ... and the methodology used.”

 [Heller](#), 167 F.3d at 153; see also  [Oddi](#), 234 F.3d at 158 (affirming exclusion of opinion based essentially on nothing more than expert's experience and training in field).

Dr. Bloor's methodology simply fails to satisfy many of the factors set forth by *Daubert* and its progeny for the court to consider in determining reliability. Most importantly, Dr. Bloor's semi-quantitative scoring methodology has not been demonstrated to have a known or potential rate of error, to be testable, or to have any control standards.


*13 First, both parties acknowledge that the error rate of Dr. Bloor's technique is unknown. (Mot. re: Bloor at 19; Resp. to Mot. re: Bloor at 13.)

Second, the court is not convinced that Dr. Bloor's methodology is testable. See  [Oddi](#), 234 F.3d at 156 (citing  [Daubert](#), 509 U.S. at 593) (emphasizing that key question in determining whether technique is scientific knowledge is whether it can be tested). Dr. Bloor never actually assigned a numerical score to any of the slides.

Rather, he scored his recategorizations of the narrative descriptions of the slides months after his review of the actual slides. Although Drs. Boivin, Fisher and Wagner also employed visual analyses of the slides, this does not make Dr. Bloor's methodology, consisting of recording of narrative descriptions, categorization of those descriptions, and numerical scoring of those categorizations, testable. In fact, when blinded to the exposure status of each rat during his trial deposition, Dr. Bloor could not reproduce his own results when asked to re-score the slides using his own method. (PTO 1468 App. re: Bloor I, Tr. 2/21/00 at 836–838; Tr. 12/13/00 Exs. F–4 & F–5; Mot. re: Bloor at 20–22 & Ex. 9.)

Third, as noted above, Dr. Bloor's re-analysis of the slides was unblinded, i.e., he was aware of whether a particular slide he was analyzing came from a rat exposed to dexfenfluramine and the level of exposure, or whether that slide came from a rat in one of the unexposed control groups. (Tr. 12/12/00 at 234–35.) Thus, there were no control standards utilized by Dr. Bloor. Dr. Bloor himself acknowledges that blinding is generally utilized to remove bias, and that the possibility of bias increases with the subjectivity of the analysis. (PTO 1468 App. re: Bloor I, Tr. 10/5/99 at 258–59.) Dr. Bloor's attempt, during his trial deposition testimony, to reproduce his own results actually yielded an increased finding of fibrosis in the slides from the unexposed control groups. (Tr. 12/13/00 Ex. F–4.)

Plaintiffs contend that Dr. Bloor's analysis was not blinded because, when he reviewed the slides in France, he was permitted to look at only one slide at a time and that he had to request the specific slide he wanted to see, specifying which group of rats the slide was to come from. The court fails to see how the fact that the conditions under which Servier required Dr. Bloor to operate, preventing Dr. Bloor from blinding himself to the treatment status of each particular rat, impacts this court's inquiry into the reliability of Dr. Bloor's methodology. That it was the conduct of an adverse party which prevented Dr. Bloor from blinding himself does not make his testimony any more reliable or render the issue of blinding irrelevant.

Also, Dr. Bloor's failure to account for the presence of confounding factors such as age, diet, stress, and other causes of cardiac pathology casts doubt on the usefulness of his method in determining whether dexfenfluramine caused the myocardial fibrosis in the rats' hearts and the reliability of opinions based thereon. See  [Kelley v. Am. Heyer-Schulte Corp.](#), 957 F.Supp. 873, 878 (W.D.Tex.1997) (noting that “an







observed association between exposure ... and a condition may reflect a true cause-effect relationship or a spurious finding ... [and][t]o distinguish between these alternatives, it is necessary first to consider the effect of confounding factors”); Reference Manual on Scientific Evidence 369 (2d ed.2000) (stating that even when association between exposure and disease exists, it must be determined “whether the exposure causes the disease or whether the exposure and disease are caused by some other confounding factor”). Significantly, although Dr. Bloor acknowledged that the incidence of myocardial fibrosis increases with age, he assumed that all of the rats were the same age at the end of the study, when the facts show that over half of them did not survive until the end of the study. (PTO 1468 App. re: Bloor I, Tr. 10/4/99 at 223, Tr. 10/5/99 at 468 & 494–95; Mot. re: Bloor Ex. 8.) Many of those that did not survive, and thus did not age with the rats that survived until termination of the study, were included within the study. *Id.* Ex. 8, ¶ 31. According to Dr. Fisher, AHP’s expert pathologist, this failure to account for age led to Dr. Bloor’s failure to recognize that the severity of myocardial fibrosis within treatment groups correlated to increased age.¹⁷ *Id.* Ex. 15 at 346–47; Tr. 12/13/00 Ex. F–3.



*14 Moreover, Dr. Bloor acknowledges that he failed to start with a null hypothesis. Dr. Bloor began his analysis of the slides with the presumption that dexfenfluramine was cardiotoxic and attempted to confirm that assumption, rather than starting with the assumption that dexfenfluramine was not cardiotoxic and analyzing the slides to see if the data contradicted that assumption. As Dr. Fisher testified, Dr. Bloor’s presumption inverted the scientific method. (Tr. 12/13/00 at 7–9.) In the court’s opinion, this further undermines the reliability of what Dr. Bloor acknowledges to be a subjective methodology.

The court recognizes that pathologists routinely employ some form of subjective review of histological slides. However, even assuming that Dr. Bloor’s technique of unblinded visual observation, recording of narrative descriptions, categorization of those descriptions and numerical scoring of the categories is commonly employed by pathologists, general acceptance in the relevant scientific field is only one of many factors that the court can consider with regard to reliability. For purposes of the instant motion, this factor holds little weight in light of the fact that Dr. Bloor, in employing a methodology that he acknowledges to be subjective, reached differing conclusions at different times regarding the extent

of fibrosis exhibited in the *same* slides. (Tr. 12/12/00 Exs. F–4 & F–5.)

Although Study 1781 reported increased levels of fibrosis in the rats’ hearts, its primary purpose was to look for tumor pathology, i .e., to test for potential carcinogenic properties of dexfenfluramine. *Id.* at 216–17. Because it was not designed to assess the potential cardiotoxic effects of dexfenfluramine, the court questions the reliability of an opinion, based primarily on the data from this study, that dexfenfluramine is cardiotoxic.

The court also notes that several courts have discounted the reliability of experts who, like Dr. Bloor, formed their opinions entirely within the context of litigation.  *Whelting v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir.1998) (opinion available at 1998 WL 546097, at * 3);  *Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 597 (9th Cir.1996);  *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir.1995);  *Nelson v. Am. Home Prods. Corp.*, 92 F.Supp.2d 954, 967 (W.D.Mo.2000);  *Metabolife Int’l, Inc. v. Wornick*, 72 F.Supp.2d 1160, 1168–69 (S.D.Cal.1999);  *Muzzey v. Kerr–McGee Chem. Corp.*, 921 F.Supp. 511, 519 (N.D.Ill.1996); see Tr. 12/12/00 at 211 (noting that Dr. Bloor’s report was drafted entirely within litigation context).

Lastly, Dr. Bloor’s analysis of the slides from Study 1781 was never published in the peer reviewed scientific literature. Tr. 12/12/00 at 212; see  *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 742 n. 8 (including peer review as factor to consider). Although Plaintiffs insist that his analysis was “peer reviewed” because it was scrutinized by two other experts retained in this case, Drs. Fisher and Wagner, the court does not believe that review by experts retained by either party in the context of litigation is the type of “submission to the scrutiny of the scientific community” contemplated by *Daubert* and its progeny.¹⁸ See  *Daubert*, 509 U.S. at 594 (noting that such scrutiny increases likelihood that substantive flaws in methodology will be detected).

*15 Plaintiffs appear to argue that because Dr. Bloor was only seeking to confirm the conclusions reached by Dr. Boivin, inquiry into many of these reliability factors is somehow irrelevant. It is true that in Study 1781, Dr. Boivin concluded that there was a statistically significant increase of

focal fibrosis in the rats' hearts. To the extent that Dr. Bloor renders his own opinions about the levels of fibrosis exhibited in the slides, an inquiry into the methodology through which he arrives at those opinions is necessary and appropriate. The court fails to see how the fact that Dr. Bloor relies on the raw data from Study 1781, i.e., the histological slides, somehow makes his methodology in conducting an analysis of that data irrelevant. Dr. Bloor's opinion that the slides demonstrate a statistically significant level of fibrosis, beyond what was reported by Dr. Boivin, cannot withstand *Daubert* scrutiny because his methodology is unreliable.

It follows that Dr. Bloor's opinion concerning dexfenfluramine's causation of myocardial fibrosis in humans must be excluded because it is based primarily on his unreliable analysis of the slides from Study 1781. The court can also easily preclude this testimony because Dr. Bloor has not adequately explained how or why he can reliably extrapolate the results of the rat study to human beings. See Pretrial Order No. 1351 at 27–29 (excluding opinion on causation of PPH and VHD in humans based on in vitro studies of animals injected with phentermine because experts could not cite reliable support for extrapolation theory); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144 (1997) (affirming exclusion of plaintiff's experts' opinions on causation in humans because plaintiff never explained how and why experts could extrapolate their opinions from animal studies far removed from circumstances of plaintiff's exposure); *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387, 1410 (D.Or.1996) (citations omitted) (stating that “[e]xtrapolations of animal studies to human beings are generally not considered reliable in the absence of a scientific explanation of why such extrapolation is warranted”). Plaintiffs submit that this extrapolation is proper because Study 1781 was relied on by the FDA when it approved Redux for human use. However, the FDA primarily engages in a process of risk assessment rather than determining causation, and the relevance to causation of evidence used to assess risk is not clear.¹⁹ Also, Study 1781 was primarily designed to test for, and presumably assess the risk of, carcinogenicity from dexfenfluramine, not the risk of cardiotoxicity. Further, the other data relied on by Dr. Bloor in forming his causation opinion are anecdotal case reports that, as AHP correctly points out, are universally recognized as insufficient and unreliable evidence of causation. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir.1999); *Hollander v. Sandoz*

Pharms., Inc., 95 F.Supp.2d 1230, 1237 (W.D.Okla.2000); *Glastetter v. Novartis Pharms. Corp.*, 107 F.Supp.2d 1015, 1030 (E.D.Mo.2000); *Nelson*, 92 F.Supp.2d at 969; *Brumbaugh v. Sandoz Pharm. Corp.*, 77 F.Supp.2d 1153, 1156 (D.Mont.1999); *Hall*, 947 F.Supp. at 1411. Accordingly, Dr. Bloor's testimony regarding causation in humans should be excluded.

*16 For the reasons discussed above, the court will exclude Dr. Bloor's testimony that, based on his interpretation of the Study 1781 slides, the increased incidence and severity of myocardial fibrosis in the rat hearts was a strong signal that dexfenfluramine was cardiotoxic and warranted further testing.

However, the court perceives no *Daubert* problem with testimony by Dr. Bloor that, based on his experience in cardiac pathology, the levels of and location of fibrosis reported by Dr. Boivin in Study 1781, if assumed to be accurate, warranted further investigation with regard to the potential of fenfluramines to cause cardiac fibrosis.²⁰ The court believes that Dr. Bloor's extensive experience in pathology qualifies him to render such an opinion, notwithstanding his lack of experience in pharmacology and toxicology. After all, it was a pathologist for the manufacturer of dexfenfluramine, Dr. Boivin, who reported the increased incidence of fibrosis in some of the rats. Thus, the court's ruling does not preclude the admissibility of such an opinion. However, notice may or may not be relevant in particular cases. Further, the law may differ among jurisdictions as to what is sufficient to constitute notice and what duty may or may not result to the notified party. Accordingly, the admissibility of any such opinion will be left to each individual remand court.

3. Dr. Oury

AHP challenges the portions of Dr. Oury's testimony regarding (1) labeling and regulatory issues and (2) pathology.²¹

1. Labeling and Regulatory Issues

Dr. Oury testified that AHP: 1) failed to warn physicians about the risks of Pondimin and Redux; 2) failed to adequately test these drugs; and 3) failed to properly report adverse events to the FDA. (AHP's PTO 1468 Mem. in Supp. of Mot. to Exclude Expert Ops. of James H. Oury, M.D. (“AHP's PTO

1468 Mem. re: Oury”) at 3.) AHP asserts that Dr. Oury is not qualified to render these opinions because he has no familiarity with standards for drug labeling, drug testing, or adverse event reporting and has no personal knowledge of adverse event reports. *Id.* at 4. Furthermore, AHP argues that Dr. Oury's opinion was not formed through application of any reliable methodology. *Id.* at 5.

According to Plaintiffs, Dr. Oury testified that, based on his expertise as a cardiovascular surgeon, the reports of VHD in *Pondimin* users received by AHP in 1995 should have triggered further testing, evaluation and warnings concerning both *Pondimin* and Redux. (Pls.' Mem. of Law in Opp'n to Def. AHP's Mot. to Limit Expert Witness Test. of Dr. James Oury and Accompanying Exs. (“Opp'n to Mot. re: Oury”) at 9.) Plaintiffs assert that AHP mischaracterizes Dr. Oury's testimony as addressing whether AHP violated FDA regulations. *Id.* at 8.

The court concludes that these opinions should be excluded under *Daubert*. Dr. Oury admits that he has no experience or expertise in drug testing or adverse event reporting. (Tr. 12/12/00 at 50–53 & 55.) Additionally, he testified that his opinion that 100 adverse event reports which AHP received in 1995 should have triggered more warnings, evaluation and testing is based on his own personal opinion rather than any particular methodology. *Id.* at 48. Lastly, of the many hundreds of *heart valve surgeries* performed by Dr. Oury in recent years, he estimates that only about six involved patients who had ingested diet drugs and that only four of those patients exhibited the unusual valvular morphology associated with diet drugs. *Id.* at 63–65. Thus, he lacks the requisite experience and expertise to render these opinions. Accordingly, Dr. Oury's testimony concerning AHP's failure to warn about the risks associated with *Pondimin* and Redux, failure to test those drugs, or report adverse events should be excluded.

2. Pathology–Based Opinions

*17 Dr. Oury's testimony is based partly on the report of Dr. Bloor, which concluded that Servier's Study 1781 demonstrated fibrosis in the hearts of rats exposed to dexfenfluramine. AHP points out that Dr. Oury is not a pathologist and does not consider himself an expert in diagnosing abnormal changes in heart valves, and that he never reviewed the rat heart tissue slides himself. (AHP's PTO 1468 Mem. re: Oury at 7–8.)

Plaintiffs contend that Dr. Oury's testimony is offered to show that findings of fibrosis in the hearts of rats in Study 1781 gave notice to AHP that *fenfluramines* may cause similar problems in humans and that Dr. Oury will not testify as to the accuracy of the study's findings. (Opp'n to Mot. re: Oury at 13.) According to Plaintiffs, Dr. Oury's experience as a cardiac surgeon gives him expert knowledge of cardiac pathology as it relates to *heart valve surgery*. *Id.* at 15.

The court concludes that the challenged testimony concerning pathological issues lies beyond Dr. Oury's expertise. Plaintiffs correctly point out that Dr. Oury has knowledge of cardiac pathology to the extent that it relates to *heart valve surgery*. However, the court does not believe that his experience as a cardiac surgeon has endowed him with sufficient expertise in pathology to render opinions about the epidemiologic, pathologic or pharmacologic significance and implications of a finding of fibrosis in the hearts of rats exposed to dexfenfluramine. The fact that Dr. Oury regularly consults with cardiac pathologists in his practice, routinely sends them histological slides for examination, and relies on reports received from cardiac pathologists only reinforces the conclusion that Dr. Oury himself lacks sufficient expertise to opine on pathological issues. *See* Tr. 12/12/00 at 30–32 (discussing Dr. Oury's experience with pathological issues in his practice). Accordingly, AHP's motion to exclude the testimony of Dr. Oury will be granted.

4. Dr. Gueriguian

AHP challenges Dr. Gueriguian's testimony: (1) regarding pharmaceutical company conduct; (2) regarding what other FDA officials would have done with additional information such as certain ADEs; and (3) that Dr. Bloor's interpretation of the slides from Study 1781 vindicates his conclusion that AHP should have performed additional testing. The court will address each challenge seriatim.

1. Opinions Regarding Pharmaceutical Company Conduct
AHP asserts that: (1) Dr. Gueriguian testified that consumers should be warned about drugs directly although FDA regulations prohibit this; (2) and even though extensive regulations govern New Drug Application (“NDA”) formats, Dr. Gueriguian opines that companies should provide information in a clear and understandable way to the FDA. (AHP's PTO 1468 Mem. re: Gueriguian at 5–6.) According to AHP, Dr. Gueriguian is improperly testifying as to what standards should apply to AHP's conduct. *Id.* at 5.

Plaintiffs respond that Dr. Gueriguian opines that users should be able to understand drug labels as explained by the prescribing physicians, who, in turn, can advise the users only with adequate labeling. (Pls.' Opp'n to Defs.' Mot. to Limit the Expert Test. of John Gueriguian, M.D. ("Opp'n re: Gueriguian") at 14.) As to testimony about the way companies should communicate to the FDA, Plaintiffs assert that Dr. Gueriguian's experience qualifies him to testify to the standard of care for the industry and the FDA. *Id.* at 15.

*18 The court concludes that Dr. Gueriguian's testimony that drug safety surveillance is important to the public because "patients themselves should have an opportunity to voice their opinion and make a decision ... to be able to read and understand the labeling, particularly when explained by the prescribing physician" is inadmissible under *Daubert*. See PTO 1468 App. of Materials for Consideration of AHP's *Daubert* Mot. to Exclude Expert Test. of John L. Gueriguian, M.D. ("PTO 1468 App. re: Gueriguian"), Tr. 10/16/00 at 23–24 (reflecting challenged testimony). It does not appear to be based on an interpretation of FDA regulations or Dr. Gueriguian's experience in applying those regulations. The court notes that the federal government has identified the purposes and goals behind requiring accurate labels for prescription drugs in the Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

Further, this testimony runs contrary to controlling law as reflected in those regulations and the learned intermediary doctrine, which mandate that accurate warnings be directed to the physician rather than to the patient. Thus, it is not an "expert" opinion, but rather a personal opinion about what standards Dr. Gueriguian believes should apply to pharmaceutical company conduct.

The remainder of the challenged testimony is admissible under *Daubert* criteria. For example, to the extent that Dr. Gueriguian opines about how information should be communicated to the FDA and what information should be reflected in labels, as mandated by applicable regulations, he is undoubtedly qualified to do so in light of his experience as an FDA officer. If AHP wishes to challenge this testimony as misleading or confusing under Rule 403, it can do so in the remand courts. However, to the extent that AHP seeks to exclude it on *Daubert* grounds, its motion will be denied.

2. Testimony as to What Other FDA Officials Would Have Done With Additional Information Such as Certain ADEs

AHP claims that Dr. Gueriguian testified as to conclusions that the FDA's Dr. Lutwak would have drawn had he received certain ADEs, and that physicians would not have prescribed [Pondimin](#) or Redux with additional warnings on the labels. (AHP's PTO 1468 Mem. re: Gueriguian at 7–8.) AHP seeks to exclude this testimony as speculation. *Id.*

Plaintiffs state that Dr. Gueriguian testifies as to what a reasonable FDA official, such as Dr. Lutwak (the FDA's chief medical officer), would have done with the ADEs. (Opp'n to Mot. re: Gueriguian at 21–22.) Also, Plaintiffs assert that Dr. Gueriguian is an expert in labeling and can testify as to why labels are required and the consequences of inaccurate labels. *Id.* at 23–25.

The court perceives only one *Daubert* issue in this challenged testimony—whether Dr. Gueriguian can testify as to whether or not physicians would have prescribed or patients would have taken [Pondimin](#) or Redux had certain adverse event information been discussed in the drugs' labeling. Dr. Gueriguian is not qualified to opine on what decisions would have been made by the numerous physicians who prescribed diet drugs had they been provided with different labeling information. Unlike opining about what physicians in general expect to see on a label, his surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge. Accordingly, AHP's motion will be granted to the extent that it challenges Dr. Gueriguian's testimony as to whether AHP's failure to report certain information to the FDA led to more suffering and deaths of patients who were prescribed these diet drugs.

*19 On the other hand, Dr. Gueriguian is clearly qualified to testify as to what reasonable FDA officials, in the position occupied by Dr. Lutwak, would do with adverse event information. The court recognizes that Dr. Gueriguian's testimony is somewhat unclear as to whether he is offering such testimony or whether he is testifying as to what Dr. Lutwak would have done. He cannot testify as to what Dr. Lutwak would have done. He can, however, testify as to what a reasonable official in the position of Dr. Lutwak would have done. Any ambiguity in Dr. Gueriguian's testimony in this respect may be adequately ruled upon, and addressed with instructions or explanations to the jury by the trial judge. AHP's motion will be denied to the extent that it challenges this testimony, without prejudice to raise the objection in the remand courts.

3. Testimony that Dr. Bloor's Opinions Interpreting the Servier Rat Slides Vindicates His Conclusion that AHP Should Have Performed Additional Testing

AHP posits that relying on the unexamined opinions of another expert as fact is not proper. (AHP's PTO 1468 Mem. re: Gueriguian at 9.) It notes that Dr. Gueriguian is not a pathologist and has never reviewed the slides. *Id.* at 9–10.

Plaintiffs argue that Dr. Gueriguian testified that FDA medical officers routinely rely on pathologists' interpretations of animal studies in making decisions regarding approval and labeling. (Opp'n to Mot. re: Gueriguian at 25–27.) According to Plaintiffs, Dr. Gueriguian opined that Dr. Bloor was the type of expert on which the FDA would rely, and that Dr. Gueriguian's interpretation of Study 1781 is the kind of analysis that medical officers rely on. *Id.* at 27–28.

Because the court has already determined that Dr. Bloor's report is unreliable, any opinion by Dr. Gueriguian based upon that report is also unreliable and should be excluded. *See supra* at 33–45 (concluding that Dr. Bloor's opinion is inadmissible under *Daubert*). Accordingly, AHP's motion will be granted to the extent that it challenges expert testimony by Dr. Gueriguian based on Dr. Bloor's report.

5. Drs. Barst and Rich

Initially, the parties agree that both Drs. Barst and Rich are highly qualified within their particular disciplines. Thus, AHP does not challenge their qualifications to testify about the origin, symptoms, treatment and other aspects of PH and PPH, including causation of these diseases by diet drugs. Many of the opinions rendered by these witnesses then, presumably, are not being challenged. Such testimony will be admitted to the extent that it is relevant to issues before the remand courts. However, AHP challenges Dr. Barst's and Dr. Rich's testimony regarding: (1) regulatory matters; and (2) the efficacy of [Pondimin](#) and Redux for treating [obesity](#).

1. Opinions on Regulatory Matters

AHP argues that neither Dr. Barst nor Dr. Rich²² have expertise in FDA regulations that is derived from a non-litigation source, and that their expertise in diagnosing and treating PPH is irrelevant to labeling. (AHP's PTO 1468 Mem. re: Barst at 8; AHP's PTO 1468 Mem. re: Rich at 9–10.) Thus, for example, AHP claims that Dr. Rich's testimony that certain ADEs should have been reported more completely and more expeditiously to the FDA, and Dr. Barst's testimony that AHP

failed to ensure that adequate information reached healthcare providers, are inadmissible under *Daubert*. (Tr. 12/5/00 at 9–10; PTO 1468 App. of Materials for Consideration of AHP's *Daubert* Mot. to Exclude Expert Test. of Stuart Rich, M.D. (“PTO 1468 App. re: Rich”), Tr. 7/28/00 at 83–84; Mot. re: Barst at 13.) Further, AHP contends that Dr. Barst's and Dr. Rich's limited review of documents handpicked for litigation is not a reliable basis for regulatory opinions. (AHP's PTO 1468 Mem. re: Barst at 8; AHP's PTO 1468 Mem. re: Rich at 9.)

*20 Plaintiffs argue that AHP mischaracterizes these opinions. Under applicable regulations, the content of a warning must be medically and scientifically accurate. According to Plaintiffs, these opinions address the accuracy of AHP's warning; the state of medical knowledge then known by experts and AHP regarding the risk of PPH posed by [fenfluramine](#) and [dexfenfluramine](#); the seriousness of PPH; and the types of information relied on by physicians in making risk/benefit judgments about drugs. (Pls.' PTO 1468 Mem. Exs. A–2 & E–2.)

The court concludes that Drs. Barst and Rich are eminently qualified to “opine on the medical facts and science” regarding the risks of the diet drugs in question as such testimony relates to the risks of PH and PPH. (Pretrial Order No. 1332 at 27.) Thus, Drs. Barst and Rich may opine as to the labels' accuracy and the extent to which an inaccuracy or omission could either deprive or mislead a reader as to the risks of these diet drugs at the time the labeling was published.²³ *Id.* at 28.

However, testimony about whether the labels met regulatory standards is beyond the expertise of both Drs. Barst and Rich. Neither witness has anything more than incidental experience with FDA regulations addressing the approval process for labeling, the requisite content of labels, or any other issues concerning the propriety of labeling as defined by FDA regulations. *See* Tr. 12/5/00 at 84–85, 109–17 & 135–36 (reflecting nature of Dr. Rich's experience in label drafting and adverse event reporting); PTO 1468 App. of Materials for Consideration of AHP's *Daubert* Mot. to Exclude Expert Test. of Robyn J. Barst, M.D. (“PTO 1468 App. re: Barst”), Tr. 9/19/00 at 478–81 (admitting that she has no expertise in FDA regulations). Although reading the regulations from time to time and discussing them with colleagues on those occasions when a regulatory question arises is no doubt helpful in their work, this incidental experience does not qualify them as experts in the area of interpreting and applying the body of

regulations that apply here. Drs. Barst and Rich have not thoroughly reviewed, even in the context of this litigation, the FDA's regulatory scheme in a manner that would constitute a reliable methodology. Accordingly, AHP's motions will be granted to the extent that they seek preclusion of Dr. Barst's and Dr. Rich's opinions concerning AHP's compliance with FDA regulations.

2. Opinions Regarding *Obesity* and The Efficacy of *Pondimin* and Redux

AHP contends that Drs. Barst and Rich lack the expertise and reliable bases to render these opinions. (AHP's PTO 1468 Mem. re: Barst at 9–10; AHP's PTO 1468 Mem. re: Rich at 11.) Neither is an expert in treating *obesity* or in evaluating diet drug efficacy, and Dr. Rich has never prescribed a diet drug. (Tr. 12/5/00 at 121–22; PTO 1468 App. re: Rich, Tr. 7/31/00 at 363; PTO 1468 App. re: Barst, Tr. 9/19/00 at 481–82.) AHP notes that Dr. Barst relies on two documents for her opinions—one is an FDA document summarizing studies that Dr. Barst did not review, and the other is a document that summarizes a dexfenfluramine efficacy study. Dr. Rich relies on only the latter document for his efficacy opinions. According to AHP, neither Dr. Barst nor Dr. Rich reviewed relevant clinical studies or published literature. (AHP's PTO 1468 Mem. re: Barst at 9–10; AHP's PTO 1468 Mem. re: Rich at 11.)

*21 Plaintiffs assert that as physicians and cardiologists, Drs. Barst and Rich are qualified to discuss the morbidity and mortality of *obesity*, to evaluate the risks and benefits of drugs and to refer to the so called Index Study which showed little efficacy. (Pls.' PTO 1468 Mem. Exs. A–2 & E–2.) Plaintiffs claim that both Drs. Barst and Rich have reviewed the data regarding the efficacy of *Pondimin* and Redux. *Id.* Furthermore, Plaintiffs note that the FDA gave Dr. Rich the dexfenfluramine study to prepare him for a 1995 hearing, and that it was relied upon by Dr. Rich in making his opinion in this MDL 1203. (Tr. 12/5/00 at 63–64; Pls.' PTO 1468 Mem. Exs. A–2 & E–2.) According to Plaintiffs, any assertion that these witnesses should have reviewed additional documents goes to the weight, not admissibility, of their opinions. (Pls.' PTO 1468 Mem. Exs. A–2 & E–2.)

The court concludes that Drs. Barst and Rich are not qualified to opine about the efficacy of *Pondimin* and Redux for treating *obesity*. Clearly, testimony concerning the risk of PH and PPH from diet drugs is within the expertise of both of these experts. However, neither expert has sufficient experience in treating or studying *obesity* to opine on the efficacy of *Pondimin* and

Redux in inducing weight loss and reducing the comorbidities associated with *obesity*. See PTO 1468 App. re: Barst, Tr. 9/19/00 at 481–82 (admitting that she is not an expert in treating *obesity* or evaluating diet drug efficacy); Tr. 12/5/00 at 122–24 (reflecting Dr. Rich's testimony that he does not consider himself an expert in treating *obesity* and has never studied, published or taught about subject). Although Dr. Rich was asked by the FDA to render an opinion about Redux, he was requested to opine about the risks of PPH associated with the drug, not its efficacy. (Tr. 12/5/00 at 123.) Put simply, general training and experience as physicians in evaluating the risks and benefits of drugs does not translate into the specific expertise to render expert opinions about the efficacy of a specific class of drugs such as those at issue in this litigation. Accordingly, the court will grant AHP's motions to the extent that they seek to exclude testimony by Drs. Barst and Rich concerning the efficacy of *Pondimin* and Redux for treating *obesity*.

F. Dr. Sears

The court will set forth each of AHP's challenges and the Plaintiff's response, and then discuss the court's analysis and ruling.

1. AHP's Arguments

1. *The Effectiveness of Pondimin and Redux in Treating Obesity and Other Opinions Regarding the Treatment of Obesity with Medication*

AHP argues that Dr. Sears has no medical training or expertise in the medical or *pharmacological treatment of obesity* or its comorbidities, and no expertise in FDA regulation of medications. (AHP's PTO 1468 Mem. re: Sears at 4.) It asserts that his research on the dietary treatment of *obesity* has not been peer-reviewed. *Id.* at 5. AHP also claims that Dr. Sears' methodology is unreliable as he: (1) failed to review the extensive literature of published, peer-reviewed drug clinical trials; (2) rejects weight loss as a key efficacy measure of diet drugs, contrary to the unanimous position of consensus expert groups; (3) performed litigation oriented, non-peer-reviewed reanalysis of a Redux study without understanding the underlying calculations used in the study; and (4) based his conclusions on interpretations of secondary reviews of medical literature that contradict what the reviews expressly state. *Id.* at 5–8.

2. *Whether Redux Met FDA Efficacy Standards for Approval of Anti-Obesity Medications*

*22 AHP argues that Dr. Sears has no expertise qualifying him to opine on this subject. *Id.* at 12. It asserts that Dr. Sears did not research FDA approval standards or published literature on such standards, and did not review the Redux NDA record or the FDA's summary basis of approval. *Id.* According to AHP, Dr. Sears' testimony is likely to mislead the jury because he: (1) takes the efficacy opinions of FDA officials out of context; (2) confuses the issue of efficacy with the issue of risk/benefit ratio; and (3) criticizes the efficacy data presented to the FDA for failing to meet a certain criterion for average weight loss despite the fact that the criterion is invalid in Sears' own opinion. *Id.* at 12–13.

3. *AHP's Marketing Efforts and Disclosure Obligations*

Finally, AHP challenges Dr. Sears' testimony that AHP failed to fulfill its duty to fully inform the FDA and the public about the efficacy of *Pondimin* and Redux. *Id.* at 16. AHP notes that Dr. Sears disclaimed expertise on the issues of pharmaceutical company marketing or obligations to discourage off-label prescription of products. *Id.* Furthermore, it claims that Dr. Sears' methodology is unreliable because he conducted no review of AHP's marketing efforts or communications with physicians, and was unaware of relevant “dear doctor” letters. *Id.* Lastly, according to AHP, Dr. Sears implies that the data from his re-analysis of a Redux clinical study should have been submitted to the FDA because AHP should have conducted such a re-analysis. *Id.* at 16–17. AHP asserts that the FDA and the Advisory Committee showed no interest in the data that Dr. Sears claims is critical, and that he is unqualified to opine on the type of analysis appropriate in drug approval proceedings. *Id.* at 17.

2. Plaintiffs' Response

Plaintiffs respond that Dr. Sears' extensive research, writing and lecturing about the bases of *obesity* qualify him to opine on the drugs' lack of efficacy for long-term treatment, i.e., that the efficacy of AHP's drugs has not been demonstrated to equal diet and exercise in addressing comorbidities and mortality associated with excess fat. (Pls.' Mem. of Law in Opp'n to Def. AHP's Mot. to Exclude the Expert Test. of Barry Sears, Ph.D. (“Opp'n re: Sears”) at 3–4.) Plaintiffs point out that Dr. Sears' methodology utilizes AHP documents, learned journals, research and documents of others, and that he need not review all relevant literature before making an opinion. *Id.* at 4. According to Plaintiffs, Dr. Sears did not

review certain literature and studies cited by AHP because he relies partly on the “Evidence Report,” compiled by a government sponsored panel of *obesity* authorities, to discuss only those articles meeting rigorous scientific scrutiny. *Id.* at 6–7. Plaintiffs note that an expert may rely on a scientific assessment of the published literature. *Id.* at 7. Also, Plaintiffs assert that Dr. Sears does not reject weight loss (as measured by Body Mass Index (“BMI”)) as an efficacy measure, but opines that fat reduction is more important. *Id.* at 8–12. Lastly, Plaintiffs argue that Dr. Sears' re-analysis of the Redux study demonstrates that some patients lost weight but gained fat, raising an issue that should have been investigated more thoroughly. *Id.* at 13–14.

3. The Court's Analysis

*23 The court concludes that Dr. Sears' testimony concerning the effectiveness of *Pondimin* and Redux in treating *obesity* is admissible under *Daubert*, but that his testimony concerning whether Redux met FDA efficacy standards and AHP's disclosure obligations should be excluded.

With regard to testimony concerning the efficacy of diet drugs, the court notes that Dr. Sears is highly qualified in the study of *obesity* and the various factors that affect that condition, as borne out by his curriculum vitae. (Mot. of AHP Defs. to Exclude Expert Test. of Barry Sears, Ph.D. (“Mot. re: Sears”) Ex. A.) The fact that he is not a medical doctor, on its own, does not preclude him from testifying about whether or not these drugs were demonstrated to be as effective as diet and exercise in reducing fat. As Dr. Martin, AHP's counter-expert to Dr. Sears, testified, being a medical doctor is not a minimum requirement to discussing the issues of weight loss or *obesity*.²⁴ In fact, the National Institutes of Health Evidence Report on the treatment of *obesity* was compiled by a panel of 24 experts, 11 of whom were not medical doctors and many of whom had Ph.D.s. (Tr. 12/12/00 at 129–30.)

Moreover, the court is convinced that the methodology employed by Dr. Sears is reliable. His theory that diet and exercise are the most appropriate means of reducing comorbidities associated with *obesity*, as set forth in his book *The Zone*, is supported by Dr. Sears' own research as well as the scientific literature. (Tr. 12/13/00 at 129 & 140–41.) Dr. Sears' research and conclusions concerning dietary parameters, which are laid out in *The Zone*, have been peer reviewed by other researchers in the field, such as the Department of Pediatric Endocrinology at Harvard Medical

School. *Id.* at 129–30. Furthermore, Dr. Sears reviewed the studies which AHP asserted he had not, and concluded that they had no effect on his position that diet and exercise are the most effective method of reducing fat. (Tr. 12/13/00 at 157.) It appears to the court that AHP's challenges essentially go the weight accorded by Dr. Sears to certain data and his difference of opinion with Dr. Martin concerning the most appropriate factors to analyze when studying the efficacy of diet drugs. These challenges are best left to cross-examination, and do not sufficiently undermine Dr. Sears' qualifications or methodology regarding his opinion on the efficacy of diet drugs for treating obesity. Accordingly, AHP's motion will be denied to the extent that it seeks to preclude such testimony.

On the other hand, Dr. Sears clearly lacks the qualifications and methodology to opine about whether Redux met FDA efficacy criteria. He has no expertise in FDA regulations. (PTO 1468 App. of Materials for Consideration of AHP's Mot. to Exclude Expert Test. of Barry Sears, Ph.D., Tr. 10/25/00 at 115.) Nor did Dr. Sears conduct a thorough review of FDA regulations, efficacy standards for approval of diet drugs, or the Redux New Drug Application. *Id.* at 191. Accordingly, AHP's motion will be granted to the extent that it seeks to preclude Dr. Sears' testimony about whether Redux met FDA efficacy standards, or any other expert testimony about regulatory matters.

*24 Lastly, Dr. Sears is also unqualified to opine about AHP's marketing efforts and disclosure obligations. As already noted, Dr. Sears has no regulatory expertise. Nor does he have any expertise in pharmaceutical industry standards of conduct. There is no indication that he undertook any review of the data concerning AHP's marketing efforts. Thus, he has no reliable basis to say what information should have been reported to the FDA or to physicians. Accordingly, AHP's motion will be granted to the extent that it seeks to preclude Dr. Sears' testimony about marketing efforts and disclosure obligations.

IV. CONCLUSION

For the foregoing reasons, the court will grant AHP's *Daubert* motions concerning Drs. La Puma, Bloor and Oury, and grant in part and deny in part AHP's *Daubert* motions concerning Drs. Gueriguian, Hayes, Barst, Rich, and Sears.

An appropriate Pretrial Order follows.

PRETRIAL ORDER NO. 1685

AND NOW, TO WIT, this 1st day of February, 2001, upon consideration of American Home Products Corporation's motions to exclude the expert Testimony of John J. La Puma, M.D. (Doc. # 202067), Colin M. Bloor, M.D. (Doc. # 201771), James Oury, M.D. (Doc. # 201153), John Gueriguian, M.D. (Doc. # 202165), Arthur H. Hayes, M.D. (Doc. # 202164), Robyn J. Barst, M.D. (Doc. # 201797), Stuart Rich, M.D. (Doc. # 201818) and Barry Sears, Ph.D. (Doc. # 202166); the Plaintiffs' responses thereto; and AHP's and Plaintiffs' Pretrial Order No. 1468 memoranda and accompanying appendices, IT IS ORDERED that:

1. The motions to exclude the expert testimony of John J. La Puma, M.D., Colin M. Bloor, M.D. and James Oury, M.D. are GRANTED;
2. To the extent that Drs. Gueriguian, Hayes, Barst, Rich, and Sears proffer expert opinions as to the intent of AHP and/or beliefs of FDA officials as evidenced by the words and conduct of their agents, servants or employees, the motions are GRANTED. However, this ruling does not in any way preclude the introduction of otherwise admissible evidence of the intent or beliefs of AHP or FDA personnel;
3. To the extent that AHP challenges: (a) the introduction of certain documents through the reading of them into the record; (b) the manner or context in which a particular witness uses the term "serious;" (c) the injection of hearsay into trial deposition testimony; and (d) testimony as to matters not timely disclosed in an expert report, the motions are DENIED without prejudice to raise those challenges in the remand courts;
4. To the extent that AHP challenges the admissibility of the videotape of surgery performed by Dr. Oury on a patient who later became a plaintiff in this litigation, AHP's motion to exclude Dr. Oury's testimony is DENIED without prejudice to raise the challenge in the remand courts;
5. To the extent that AHP challenges: (a) Dr. Gueriguian's expert testimony about the standard of care in the pharmaceutical industry regarding the manner in which certain information should be communicated to the FDA; and (b) what FDA officials would have done with certain additional information such as particular adverse event

reports, the motion to exclude Dr. Gueriguian's testimony is DENIED;

*25 6. To the extent that Dr. Gueriguian testifies: (a) that patients should be able to read and understand labeling in order to make informed decisions; (b) about whether AHP's failure to report certain information to the FDA led to more suffering and deaths of patients who were prescribed [Pondimin](#) and Redux; and (c) that Dr. Bloor's opinions interpreting the rat slides from Study 1781 vindicate his conclusion that AHP should have performed additional testing, AHP's motion to exclude Dr. Gueriguian's testimony is GRANTED;

7. To the extent that opinions are proffered by Drs. Barst or Rich concerning: (a) the extent to which there was legal compliance with any laws or regulations governing the preparation or content of labeling or other warnings furnished by AHP in conjunction with the marketing of the diet drugs at issue; or (b) the efficacy of [Pondimin](#) and Redux for treating [obesity](#), the motions are GRANTED;

8. To the extent that AHP challenges opinions by Drs. Barst or Rich concerning the medical accuracy of [Pondimin](#) and Redux labeling at a particular point in time with regard to the risks of developing PH or PPH, the motions to exclude the testimony of Drs. Barst and Rich are DENIED;

9. To the extent that AHP challenges Dr. Sears' testimony concerning the effectiveness of [Pondimin](#), Redux, or other drugs for treating [obesity](#), the motion to exclude the testimony of Dr. Sears is DENIED;

10. To the extent that AHP challenges Dr. Sears' testimony concerning: (a) whether Redux met efficacy standards for approval of anti-obesity medications; and (b) AHP's marketing and disclosure obligations, the motion to exclude the testimony of Dr. Sears is GRANTED.

IT IS FURTHER ORDERED that the extent to which any matters in items 2 through 9 above permit the rendering of opinions by Drs. Gueriguian, Hayes, Barst, Rich, and Sears, such allowances shall be conditioned upon a determination by the trial court that such matters are relevant and that the evidence upon which any opinion stands be received into evidence at the trial.


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Footnotes

- 1 Pondimin is the brand name for the diet drug fenfluramine.
- 2 Redux is the brand name for the diet drug dexfenfluramine.
- 3 See  [Daubert v. Merrell Dow Pharms., Inc.](#), 509 U.S. 579, 589 (1993) (discussing standard for admissibility of scientific evidence).
- 4 For purposes of this Memorandum and Order, the court will not list or discuss the testimony of any of these experts to which there is no *Daubert* challenge.
- 5 These depositions are referred to by the parties as "preservation depositions."
- 6 These include all of the challenges made to the testimony of Dr. Hayes.
- 7 The court will refer to these issues collectively as "corporate intent" testimony.
- 8 These challenges do not involve the qualifications of the experts or the reliability of the methodologies through which they arrive at their conclusions, even though *Daubert* obviously requires that scientific evidence be admissible under other applicable rules, such as [Federal Rule of Evidence 403](#).
- 9 Thus, AHP's motions to exclude certain testimony of Drs. Hayes and Rich on this ground will be denied. The motion to exclude Dr. Barst's testimony concerning obesity and the efficacy of Pondimin and Redux, also challenged as not having been timely disclosed, will be granted on other grounds. See *infra* § III(E)(2).

- 10 Clinical medical ethics “seeks to identify and analyze and resolve ethical problems as they arise in health care generally.” (Tr. 12/5/00 at 154.)
- 11 AHP also challenges Dr. Oury’s use of the term “unconscionable” to describe AHP’s conduct and his testimony that AHP acted in conscious disregard of the health and safety of consumers. This challenge falls within the rubric of “corporate intent.” Accordingly, AHP’s motion will be granted to the extent that it seeks to exclude Dr. Oury’s expert testimony that AHP acted unconscionably.
- 12 The Rule provides: “[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.” [Fed.R.Evid. 702](#).
- 13 The Third Circuit has listed other factors to consider as well. Together, these factors are:
- (1) whether a method consists of a testable hypothesis;
 - (2) whether the method has been subject to peer review;
 - (3) the known or potential rate of error;
 - (4) the existence and maintenance of standards controlling the technique’s operation;
 - (5) whether the method is generally accepted;
 - (6) the relationship of the technique to methods which have been established to be reliable;
 - (7) the qualifications of the expert witness testifying based on the methodology; and
 - (8) the non-judicial uses to which the method has been put.
-  [Oddi v. Ford Motor Co.](#), 234 F.3d 136, 156 (3d Cir.2000) (quoting  [In re Paoli R.R. Yard PCB Litig.](#), 35 F.3d 717, 742 n. 8 (3d Cir.1994)).
- 14 The court recognizes that although AHP is not a direct participant in the informed consent dialogue, its knowledge could find its way into the informed consent equation. To that extent, disclosure of that knowledge may become important in this litigation.
- 15 The myocardium is the middle muscular layer of the heart wall. Webster’s Third New International Dictionary 1495 (1971).
- 16 Technically, the null hypothesis is “a hypothesis that there is no difference between two groups from which samples are drawn.” Reference Manual on Scientific Evidence 167 (Federal Judicial Center 2d ed.2000). Dr. Bloor hypothesized that there was a difference in cardiac pathology between the groups of exposed rats and the control groups of unexposed rats.
- 17 Dr. Peter Fisher, an anatomic pathologist specializing in cardiovascular pathology, was AHP’s responsive expert to Dr. Bloor.
- 18 Dr. Bloor’s report was reviewed by Professor of Pathology Dr. Grover Hutchins of the Johns Hopkins Medical Institutions, who indicated in a letter that Dr. Bloor’s report would be acceptable for publication. However, Dr. Hutchins has been retained by Plaintiffs in connection with this litigation, and Dr. Bloor stated that he thought that this unsolicited letter by Dr. Hutchins was inappropriate. (Tr. 12/12/00 at 213.)
- 19 For example:
- [N]ot all would agree with [the] assumption that whatever is relied upon in assessing risk is automatically relevant to proving causation in a court of law. Proof of risk and proof of causation entail somewhat different questions because risk assessment frequently calls for a cost-benefit analysis. The agency assessing risk may decide to bar a substance or product if the potential benefits are outweighed by the possibility of risks that are largely unquantifiable because of presently unknown contingencies. Consequently, risk assessors may pay heed to any evidence that points to a need for caution, rather than assess the likelihood that a causal relationship in a specific case is more likely than not.
- Reference Manual on Scientific Evidence 33 (Federal Judicial Center 2d ed.2000).
- 20 The court is not aware of whether such an opinion is being offered, and if so, whether it is being challenged.
- 21 Challenges to the admissibility of the videotape of surgery performed by Dr. Oury on a patient who later became a plaintiff in this litigation should be raised and addressed in the remand courts.
- 22 Dr. Rich is both a fact witness and an expert witness in this litigation. To the extent that Dr. Rich testifies as to regulatory matters and occurrences of which he has firsthand, personal knowledge, such as his

participation in FDA advisory committee hearings, the court's ruling concerning opinions on regulatory matters is inapplicable. Any challenges to testimony rendered in Dr. Rich's capacity as a fact witness should be addressed to the remand courts.

- 23 In Pretrial Order No. 1332, the court stated that Drs. Avorn and Rubin could testify regarding “the risks and benefits of the diet drugs in question.” *Id.* at 27. In doing so, the court did not rule that Drs. Avorn and Rubin could testify about the efficacy of these drugs for treating obesity. By efficacy, the court means a drug's ability to produce the effect that the manufacturer represents it will have if taken properly. Certainly, “benefits” could include a drug's efficacy. However, in Pretrial Order No. 1332, the court addressed testimony concerning labeling, and the entirely independent and important topic of efficacy was not before it. In addressing any reliance on Pretrial Order No. 1332 to support an argument that Drs. Avorn and Rubin should be permitted to testify about the “benefits” of diet drugs, the remand courts should consider the context in which their testimony, and the challenges to it, were presented to this court. That is to say, the court's ruling in Pretrial Order No. 1332 should be read as permitting Drs. Avorn and Rubin to refer to, but not necessarily opine about, the benefits of diet drugs to the extent that those benefits are addressed in the drugs' labeling.
- 24 Dr. Louis F. Martin is Professor of Surgery and Professor of Public Health and Preventable Medicine at the Louisiana State University School of Medicine in New Orleans. (Tr. 12/12/00 at 90–91 & Ex. M–1.)

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